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10/521,097	11/04/2005	Ralf-Christian Schlothauer	14923.0024	7026
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EXAMINER				
TONGUE, LAKIA J				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/521,097

**Applicant(s)**

SCHLOTHAUER ET AL.

**Examiner**

LAKIA J. TONGUE

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 10-14, 23, 25, 30, 31 and 35-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15-22, 24, 26-29 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/13/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I claims 1-11, in the reply filed on February 7, 2008 is acknowledged.

Applicant's traversal of further elected *Lactobacillus sake* strain 570 is acknowledged. Applicants argue that:

1) Since the Examiner has deemed each group to read on patentably distinct microorganisms, it follows that an election of a microorganism would be an election of species. Applicants respectfully request that the Examiner clarify this matter.

Applicant's arguments have been considered but are not deemed persuasive.

With regard to Point 1, Claims 1 and 4 are being treated as linking claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-43 are pending. Claims 10-14, 23, 25, 30, 31, 35, 36, 38 and 40 have been withdrawn from further consideration as being drawn to non-elected inventions. Claims 37, 39 and 41-43 were previously withdrawn from consideration for being drawn to non-statutory use claims. Claims 1-9, 15-22, 24, 26-29 and 32-34 are currently under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on January 13, 2005 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto. The listing of references in the specification is not a proper

information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Specification***

3. The use of the trademarks Dionex, CMD and Glucidex on pages 44 and 51 have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

4. Claims 24, 26, 33 and 34 are objected to because of the following informalities: Claims 24, 26, 33 and 34 recite non-elected inventions. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9, 15-22, 24, 26-29 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rendered vague and indefinite by the use of the terms "organoleptic properties". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitute "organoleptic properties"? As written, it is impossible to determine the metes and bounds of the claimed invention.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The claimed invention is directed to non-statutory subject matter. Claims 1, 3-9, 15-17 and 19-20 are drawn to a composition comprising a viable lactic acid microorganism. The claim reads on a product of nature. Consequently, the claim does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte

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Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Inoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4-6, 15-21, 24, 26, 27, 29 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Den Berg et al. (WO 94/12656).

The rejected claims are drawn to a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme.

Van Den Berg et al. disclose the use of *Lactobacillus sake* like strains, which produce exopolysaccharides (see abstract). Van Den Berg et al. disclose that the

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composition can be used as an additive for food products or in medical, pharmaceutical and cosmetic application as well as used for *in situ* production of said composition in a dairy liquid medium (see page 3, lines 30-38). Lastly, Van Den Berg et al. disclose that the cultures containing an EPS can advantageously be incorporated into dairy ingredients (see page 4, lines 1-5).

Claim limitations such as “for consumption”, “is used to ferment milk and produce a yogurt like ingredient containing structure forming EOS and/or nutritional oligosaccharide” and “to reduce the production of gas by the gastrointestinal microorganisms when used as ingredients to products for consumption ” are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

With regard to claims 24, 26, 33 and 34, it should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in

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an unexpected manner. See In re Thorpe, 227 USPTO 964 (CAFC 1985); In re Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPTO 685 (CCPA 1972).

Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Therefore the process limitation is met by the teachings of the prior art. Consequently, the EPS is necessarily capable of being modulated; necessarily modulated by the number of viable lactic acid microorganisms, the length of the fermentation process, the incubation temperature, the pH or the acceptor molecule maltose; necessarily improves the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of food; and necessarily acts as a prebiotic.

8. Claims 1-4, 15-20, 24, 26 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Geel-Schutten et al. (Appl Microbiol Biotechnol, 1998; 50: 697-703).

The rejected claims are drawn to a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme.



Geel-Schutten et al. disclose a composition comprising viable lactic acid bacteria from *Lactobacillus* strains, which produce EPS. Geel-Schutten et al. disclose that said bacteria produce glycosyltransferase enzymes, which catalyse the transfer of glucosyl or fructosyl residues from sucrose to glucan or a fructan polymer respectively (see page 701, 2<sup>nd</sup> column). Moreover, Geel-Schutten et al. disclose that sucrose was an excellent substrate for abundant EPS synthesis and that the EPS production increased with increasing sucrose concentrations and involved extracellular surase-type enzymes. Geel-Schutten et al. disclose that the monosaccharide composition of EPS produced by *Lactobacillus reuteri* varied with growth (see abstract). Lastly, Geel-Schutten et al. disclose that the main constituent of EPS molecules is glucose (see page 698, 2<sup>nd</sup> column). Absent evidence to the contrary the claimed composition is modulated by the number of viable lactic acid microorganism, the length of the fermentation process, the incubation temperature, the pH or the acceptor molecule maltose.

Claim limitations such as "for consumption", "is used to ferment milk and produce a yogurt like ingredient containing structure forming EOS and/or nutritional oligosaccharide" and "to reduce the production of gas by the gastrointestinal microorganisms when used as ingredients to products for consumption " are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

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difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

With regard to claims 24, 26, 33 and 34, it should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re Thorpe*, 227 USPTO 964 (CAFC 1985); *In re Marosi*, 218 USPTO 289, 29222-293 (CAFC 1983); *In re Brown*, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Therefore the process limitation is met by the teachings of the prior art, the EPS necessarily improves the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of food and necessarily acts as a prebiotic.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant

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to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-9, 15-22, 24, 26-29 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geel-Schutten et al. (Appl Microbiol Biotechnol, 1998; 50: 697-703) as applied to claims 1-4, 15-20, 24, 26 and 32 above, and further in view of Van Den Berg et al. (WO 94/12656).

The rejected claims are drawn to a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme.

Geel-Schutten et al. disclose a composition comprising viable lactic acid bacteria from Lactobacillus strains, which produce EPS. Geel-Schutten et al. disclose that said bacteria produce glycosyltransferase enzymes, which catalyse the transfer of glucosyl or fructosyl residues from sucrose to glucan or a fructan polymer respectively (see page 701, 2<sup>nd</sup> column). Moreover, Geel-Schutten et al. disclose that sucrose was an excellent substrate for abundant EPS synthesis and that the EPS production increased

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with increasing sucrose concentrations and involved extracellular surase-type enzymes. Geel-Schutten et al. disclose that the monosaccharide composition of EPS produced by *Lactobacillus reuteri* varied with growth (see abstract). Lastly, Geel-Schutten et al. disclose that the main constituent of EPS molecules is glucose (see page 698, 2<sup>nd</sup> column). Absent evidence to the contrary the claimed composition is modulated by the number of viable lactic acid microorganism, the length of the fermentation process, the incubation temperature, the pH or the acceptor molecule maltose.

Claim limitations such as “for consumption”, “is used to ferment milk and produce a yogurt like ingredient containing structure forming EOS and/or nutritional oligosaccharide” and “to reduce the production of gas by the gastrointestinal microorganisms when used as ingredients to products for consumption” are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

With regard to claims 24, 26, 33 and 34, it should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart

novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See In re Thorpe, 227 USPTO 964 (CAFC 1985); In re Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Therefore the process limitation is met by the teachings of the prior art, the EPS necessarily improves the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of food and necessarily acts as a prebiotic.

Geel-Schutten does not specifically teach that the viable lactic acid bacterium is *Lactobacillus sake*; that the composition is in a concentrated, freeze dried, spray dried and/or resuspended form; that the composition is added to a dairy product or a functional food; or a container comprising said composition, wherein said container has a label indicating use and/or approval for use to improve the microbial balance of the gastrointestinal tract after consumption of said product.

Van Den Berg et al. disclose the use of *Lactobacillus sake* like strains, which produce exopolysaccharides (see abstract). Van Den Berg et al. disclose that the

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composition can be used as an additive for food products or in medical, pharmaceutical and cosmetic application as well as used for *in situ* production of said composition in a dairy liquid medium (see page 3, lines 30-38).

Geel-Schutten et al. and Van Den Berg et al. disclose analogous inventions related to a composition comprising a viable lactic acid microorganism and an exopolysaccharide (EPS). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Geel-Schutten et al. with the teachings of Van Den Berg et al. because Geel-Schutten broadly disclose the use of the genus *Lactobacillus* and Van Den Berg et al. disclose the use of a specific *Lactobacillus* producing EPS strain, particularly *Lactobacillus sake*. It would be obvious to use the composition of Geel-Schutten in a food product, medical or pharmaceutical product because the prior art suggest the use of *Lactobacillus sake* and an EPS. Further, it would have been obvious to one of ordinary skill in the art at the time of invention to use the composition in a freeze dried, spray dried and/or resuspended form for the preservation of said composition. It would have been expected, barring evidence to the contrary, that the composition would be effective because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention (KSR International Co. v. Teleflex inc., 500 U.S.-, 82 US{Q2d 1385 (2007). Moreover, KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decision *Ex parte Smith*,-

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-USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396).

Moreover, it would be obvious for one of ordinary skill in the art at the time of the invention to place the claimed composition of Geel-Schutten et al. and Van Den Berg et al. into a container in order to increase ease of use. Applicants is advised that in situations where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, F.3d, 2004 WL 1068957 (Fed. Cir. May 13, 2004).

Claim limitations such as "for consumption", "is used to ferment milk and produce a yogurt like ingredient containing structure forming EOS and/or nutritional oligosaccharide" and "to reduce the production of gas by the gastrointestinal microorganisms when used as ingredients to products for consumption " are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the

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same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See In re Thorpe, 227 USPTO 964 (CAFC 1985); In re Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Therefore the process limitation is met by the teachings of the prior art, the EPS necessarily improves the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of food and necessarily acts as a prebiotic.

### ***Conclusion***

10. No claim is allowed.



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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT  
5/7/08

/Robert A. Zeman/

for Lakia J. Tongue, Examiner of Art Unit 1645

